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| 10/565,515 | 01/23/2006 | Stephen Augustyn | PB60373USw | 2676 |

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| EXAMINER |
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OSTRUP, CLINTON T

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| ART UNIT | PAPER NUMBER |
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01/05/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/565,515 | Applicant(s) AUGUSTYN ET AL. | |
| | Examiner CLINTON OSTRUP | Art Unit 3771 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 70-88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 70-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 70-88 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/23/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to the amendment filed October 26, 2009. As directed by the amendment, claims 1-69 have been cancelled and claims 73-88 have been added. Thus, claims 70-88 are pending in this application.

Election/Restrictions

2. Applicant's election without traverse of Group II, claims 70-72 in the reply filed on October 26, 2009 is acknowledged.

Claim Objections

3. Claims 70, 72-73, 81, and 86 are objected to because of the following informalities: it is unclear if the "each" having multiple distinct medicament dose portions or pockets is referring to the dispenser or the carriers. To obviate this rejection, the examiner respectfully suggests applicant consider add the term "dispenser" or "carrier" after the term "each".

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 70-71, 73-79, and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies et al. (WO 01/97886) in view of Braithwaite (WO 01/17595) and further in view of Hickey et al (WO 01/68169 A1).

Davies teaches a medicament dispenser (Figures 1a-2b) for containing an elongate form of a medicament carrier (elongate blister strip as described on page 4, lines 21-27), each medicament carrier having multiple distinct medicament dose portions (metered dosages) carried thereby, said dispenser having a housing (body 10), and within said housing a dispensing mechanism (page 4, line 29 - page 5, line 20) for dispensing the distinct medicament dose (metered dosage) portions carried by the medicament carrier (elongate blister strip), said mechanism comprising, at least one receiving station (dose mover moves dose to dispensing position) for receiving medicament carrier (elongate blister strip); a release (dose liberator) for releasing a distinct medicament dosage (metered dosage) portion from the medicament carrier (elongate blister strip) on receipt thereof by said receiving station; an outlet (dispensing outlet), positioned to be in communication with the distinct medicament dose portions (metered dosages) releasable by said release; and at least one indexer (page 6, line 26 - page 7, line 2) for individually indexing the distinct medicament dose (metered dosages) portions of the medicament carriers (elongate blister strip), wherein said dispenser further comprises a movable cover (30) that couples to the dispensing mechanism (abstract) such that movement of said cover (30) actuates one or more components of the dispensing mechanism (movement of the cover is coupled with movement of the dose mover).

Davies also discloses that medicaments can also be delivered in combinations, but lacks the specific teaching of more than elongate blister strip being used in the device.

Braithwaite teaches a drug delivery device that utilizes a rotatable device comprising metered dosage packs for delivering single or combination therapy using two independent medicament carriers. See: page 4, lines 6-31 and figures 4a-4b, 7, and 12.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device disclosed by Davies, by utilizing a plurality of medicament carriers, as taught by Braithwaite, in order to obtain a device capable of delivering a combination of individually packaged medicaments to users in order to provide a customizable combination of medicaments using a well known medicament carrier.

Hickey is being used as a teaching reference to demonstrate the interchangeability of disk and elongate strips as being known in the art and the modification of the device to accommodate an elongate strip instead of a disk is an obvious design consideration to one of ordinary skill in the art. See: figures 1, 2, and 4-7B.

Regarding claim 71, Davies discloses a movable cover (30) as being coupled to said release (dose liberator) and said at least one indexer (page 6, line 26 - page 7, line 2) for actuation thereof.

Regarding claims 73 and 83, Davies discloses a device with a moveable cover that is simple and straightforward to "prime" for use by a patient. See: paragraph bridging pages 2 & 3. The device comprises a movable cover (30) for the outlet (12), wherein the cover (30) is movable from an at rest position (closed as shown in figure

1a), in which the cover covers the outlet, to a primed position (during movement of cover just after the position shown in figure 1a to just prior to the position shown in figure 1b) and then an actuated position (open as shown in figure 1b) to uncover the outlet (12), and couples to the dispensing mechanism (dose mover) such that: movement of said cover from the primed position to the actuated position actuates one or more components of the dispensing mechanism (by movement of the dose mover), and movement of said cover from the at rest position (figure 1a) to the primed position does not actuate said one or more components of the dispensing mechanism.

Regarding claim 74, Davies discloses the movable cover (30) couples to said release (dose liberator) and said at least one indexer (page 6, line 26 - page 7, line 2) for actuation thereof.

Regarding claim 75, Davies discloses the movable cover as being coupled to the dispensing mechanism by gearing. See: paragraph bridging pages 5 & 6.

Regarding claim 76, Davies discloses a track along which the movable cover is movable from the at rest position, to the primed position and then to the actuated position. See: page 6, lines 4-7.

Regarding claim 77, Davies discloses a movable cover (30) mounted to the housing (10) for arcuate movement relative thereto from the at rest position, to the primed position and then to the actuated position. See: figures 1a-1b and page 6, lines 16-20.

Regarding claim 78, Davies discloses a track (162 of figures 2a & 2b) which is on the housing (110).

Regarding claim 79, the combined references teach least one indexer is comprised of an index wheel for each medicament carrier.

Regarding claim 84, Davies teaches the dose portions of the medicament carrier in powder form. See: page 1, lines 4-5 and page 4, lines 16-27.

Regarding claim 85, Davies teaches the outlet in the form of a mouthpiece (14).

6. Claim 72, 80-82, and 86-88 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davies et al. (WO 01/97886) in view of Braithwaite (WO 01/17595) and Hickey et al (WO 01/68169 A1), as applied to claims 70 & 73 above, and further in view of Davies et al (5,60,419).

The combined references teach all the limitations of claim 72 except the pockets on the elongate blister strip being spaced along the length of and defined between two peelable sheets secured to each other and the dispenser having a dispensing mechanism at least one peeler positioned to engage a base sheet and a lid sheet of a pocket which has been received in said opening station for peeling apart such a base sheet and lid sheet, to open such a pocket.

Davies '419 teaches a device with elongate blister strips (401 of figure 35) having pockets (402) on the elongate blister strip being spaced along the length of and defined between two peelable sheets (404 & 403) secured to each other and the dispenser (figures 13-16) having a dispensing mechanism (col. 7, lines 5-50) with at least one peeler (combined action of 471 & 470) positioned to engage a base sheet (403) and a lid sheet (404) of a pocket (402) which has been received in the opening station (486)

for peeling apart such a base sheet and lid sheet, to open such a pocket. See: figures 13-16 & 35.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of the medicament dispenser of the combined references by utilizing the elongates blister strips and peeling opening mechanism taught by Davies '410 as the separating action of the dose liberator as disclosed by Davies in order to provide a combination drug delivery device that provides one way rotational movement of the blister strips.

Regarding claim 80, the combined references utilizing the peeling opening mechanism of Davies '419 teaches a release that comprises a take-up spindle for each medicament carrier.

Regarding claim 81, the combined references teach a medicament dispenser comprising plural blister strip form medicament carriers (See rejection of claim 70 above), each having multiple distinct pockets for containing medicament dose portions, wherein said pockets are spaced along the length of and defined between two peelable sheets secured to each other, said dispensing mechanism comprising, an opening station for receiving a pocket of each of said medicament carriers; and at least one peeler positioned to engage a base sheet and a lid sheet of a pocket which has been received in said opening station for peeling apart such a base sheet and lid sheet, to open such a pocket; and wherein the outlet is positioned to be in communication with an opened pocket and through which a user can access a medicament dose portion from such an opened pocket (See: rejection of claim 72 above); and the at least one indexer

is for individually indexing the distinct pockets of each of the plural medicament carriers.
See: Davies '419 figures 13-16 and 35.

Regarding claims 82 and 86, the combined references teach a medicament dispenser wherein Davies '419 teaches a blister strip the dispensing mechanism comprises a lid take-up spindle (471) for winding up the used lid sheet (404) of the blister strip (401) thereon and an index wheel (416) for indexing the blister strips (401) and wherein the movable cover (30 of Davies) is coupled to the dispensing mechanism such that movement of the movable cover from the at rest position (figure 1a of Davies) to the primed position does not result in any rotation of the lid take- up spindles and index wheels, but further movement of the movable cover (figure 1b of Davies) to the actuated position results in sufficient rotation of the lid take-up spindles and index wheels to advance each blister strip by one pocket distance and the leading pocket thereof to be peeled open and brought into communication with the outlet. See: col. 7, lines 5-50 of Davies '419.

Regarding claim 87, Davies teaches the dose portions of the medicament carrier in powder form. See: page 1, lines 4-5 and page 4, lines 16-27.

Regarding claim 88, Davies teaches the outlet in the form of a mouthpiece (14).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Allan et al (WO 03/024514); Hodson et al (5,619,984); Hodson et al. (5,740,793); Anderson et al (2005/0172964); Crowder et al (6,889,690); Eisele et

al (5,921,237); Morita et al (4,735,358); Haikarainen et al (WO 00/64519); Koskela et al. (WO 00/64520) which all discloses metered dose inhalers.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Steven O. Douglas/
Primary Examiner, Art Unit 3771